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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	2004P00610WOUS	7279

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
03/15/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2 and 5-14* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2 and 5-14* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 5 - 9, and 11 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Haim et al. (US 2002/0013615 A1).

Regarding Claim 1, *Haim et al.* (hereinafter *Haim)* discloses a catheter apparatus for therapy, such as therapeutic occlusion of an area of a heart, the catheter apparatus comprising: a catheter ***(figs. 1A and 1B, (20))*** configured (i.e., comprises a hallow needle ***(24)*** at catheter's distal end ***(22)***) to inject a filling material into the aneurysm. See also paragraphs [0018], [0098 – 0099].

Haim suggests also *active* locators ***(32, 34)*** located at the tip of the catheter that is configured to provide coordinates to determine spatial position and orientation of the catheter ([0104]).

There is also a pump ("dispenser," ***(54)***) configured to controllably supply filling material to the catheter *([0020], [0038], [0108 – 0109], [0119]).*

Haim suggest also a monitor ("contact or pressure sensor," ***(36)***) connected to the active locator and the pump, wherein the monitor is configured to monitor the spatial position and/or orientation of the catheter to detect emergence of the tip of the catheter from the aneurysm during the injection of the drug into the aneurysm by monitoring and/or ensuring that there is contact

between a pressure sensor and region of interest; and configured to stop the supply of the drug in response to the detected emergence (or non-contact) ([0105 – 0113]).

Regarding Claim 2, Haim suggests the catheter apparatus, wherein the active locator comprises a magnetic field sensor ([0021], [0023], [0104]).

Regarding claims 5 and 8, Haim suggests a catheter, a pump device and an electromagnetic locating device, and monitoring capabilities for monitoring the spatial position and/or orientation of the catheter based on the provided coordinates from the locator fitted on the tip of the catheter for detecting emergence of the catheter from the region of interest during injection of the filling material into the aneurysm, and thereupon stopping the supply of the drug (please see rejections of claims 1 and 2).

Regarding Claim 6, The apparatus as claimed in claim 5, wherein the monitoring unit comprises a memory having a road map stored therein ([0110]), and a recorder for recording the measured position of the locator using the road map ([0111]).

Regarding Claim 7, Haim discloses, via incorporation of *US 5,568,809* (paragraph [0105]), that the apparatus of Claim 5 comprises an imaging device, such as X-ray, NMR, ultrasound, etc. ('809: col. 3, lines 43 - 60 and col. 5, lines 31 - 38).

Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Haim discusses a locating device that works in conjunction with a magnetic field sensor device, then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense (see rejection of Claim 2). The generation of an electromagnetic field that is spatially and/or temporally inhomogeneous is commonplace, as is known in the art.

Regarding Claim 11, Haim suggests a method of controlling the supply of a plugging material to a catheter employed in the therapeutic embolization of an aneurysm, the method comprising the acts of: determining a position and/or orientation of a tip of the catheter from coordinates provided by an active locator fitted thereon; automatically monitor the spatial position and/or orientation of the catheter based on the coordinates provided by the locator; and stopping the supply of the plugging material to the catheter if emergence of the catheter from the aneurysm is detected based on the monitored spatial position and/or orientation of the catheter (see rejections of claims 1, 2, 5, 8).

Regarding Claim 12, Haim teaches that the position of the locator is recorded using a road map of locator positions, the detecting of the emergence of the catheter from the aneurysm further being based on the road map *(see rejection of Claim 6)*.

Regarding Claim 13, Haim et al. teaches, via incorporation of US 5,568,809 (mentioned in paragraph [0105]), that the catheter and the aneurysm are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent ('809: col. 3, line 65 – col. 4, line 24). See also rejection of claim 7.

Regarding Claim 14, Haim teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haim as applied to claim 5 above, and further in view of Pritchard et al. (US 2005/0220882 A1).

Regarding Claim 10, Haim teaches each and every limitation of the claim, as discussed above in reference to claim 5.

However, Haim differs from Claim 5 in that Haim does not teach that the plugging material can comprise a curable polymer material, plastic beads, a plastic coil, a hydrogel and/or a fibrin sponge.

Nonetheless, Pritchard et al. teaches that a plugging material may comprise a hydrogel in a particular shape of form "for plugging a void." Pritchard et al. suggests also that other materials art equivalent to the aforementioned materials (such as "plugs, tampons, packing strips, sheets, particles, spheres, blocks, cubes, cylinders, and cones") may be used.

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Haim and Pritchard et al. before one at the time the invention was made, to modify the device for injecting filling material of Haim with the filling material teachings of Pritchard et al. to provide user flexibility in type of materials used.

Response to Arguments

3. Applicant's arguments filed December 27, 2011 have been fully considered but they are not persuasive.

Applicant argues that on close inspection of the prior art, Applcaint fails to see a connection between the dispenser 54 and the pressure sensor 36. The monitor recitation

of the claims must be connected to the pump so as "to stop the supply of the filling material in response to the detected emergence" (i.e., emergence of the tip of the catheter from the aneurysm during the injection of the filling material into the aneurysm), as recited in claim 1.

Examiner disagrees and points out respectfully that both the dispenser (pump (54)) and monitor (pressure sensor (36)) is disposed connected to the catheter in some way. Therefore, the pump and the monitor are connected to each other via the catheter. Furthermore, the pump stops the supply of drug upon emergence or non-contact of the catheter tip based upon the monitoring of the monitor (or sensor) ([0105 – 0113]).

Applicant argues also that "Haim does not teach, disclose, or suggest that the sensor 36 or any other device '"is configured to monitor the spatial position and/or orientation of the catheter based on the provided coordinates from the locator to detect emergence of the tip of the catheter from the aneurysm during the injection of the filling material into the aneurysm,' as for example recited in claim 1. Even without examination of Haim's text, it will be understood by these skilled in the art that a contact or pressure sensor cannot 'detect emergence of the tip of the catheter' because emergence or exit does not create touching, other contact, or pressure."

Examiner disagrees and points out respectfully that in paragraphs [0071] and [0111], Haim discusses "receiving and analyzing signals from the contact sensors (36) for ensuring positive contact between the catheter's distal end and the endocardium… circuitry receives readings from the position sensor (36)…and to the extent that position coordinates thus determined remain substantially constant… it is assumed that distal end (22) [of the catheter] is

in positive contact with the endocardium." This is enough to suggest that Haim reads on the claim feature in question.

Applicant argues that "Haim does not teach, disclose or suggest stopping the supply of the filling material when the filling material when 'emergence of the tip of the catheter from the aneurysm' is detected as recited in the claims. It is noted that non-contact is not the same as detection of 'emergence of the tip of the catheter from the aneurysm'."

Examiner disagrees and points out respectfully that if the distal end or tip of the catheter has lost contact from the cardiac tissue where the aneurysm has occurred, drug supply is halted ([0028]). Haim teaches also monitoring situations of occlusions or other blockage in ducts while administering the drug ([0102]). Furthermore, Applicant, Examiner notes, has not explained why "non-contact is not the same as detection of 'emergence of the tip of the catheter from the aneurysm." Examiner, therefore, holds that Haim reasonably suggests the present features of the claims in question.

Pritchard teaches the features of the claim(s), as presented above. It should be noted that, with respect to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777